DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service
Food and Drug Administration

9/463d

19900 MacArthur Blvd., Ste 300
Irvine, California 92612-2445
Telephone (949) 798-7600

July 2, 2001

CERTIFIED MAIL - RETURN RECEIPT REQUESTED

WARNING LETTER

Ron Loew, President
Brown Bag Sandwiches, Inc.
32124 Paseo Adelanto #3
San Juan Capistrano, CA 92675

W/L 62-01

Dear Mr. Loew:

During an inspection of your manufacturing facility located in San Juan Capistrano, CA conducted between June 7 and 12, 2001, we found that you manufacture and distribute ready to eat food products, including pre-packaged sandwiches, under the following labels:

1. The Brown Bag Sandwich Company
2. [redacted]
3. [redacted]

During the inspection, we collected a number of samples including unopened ingredients, sliced meats and cheeses, and finished products; these were analyzed for *Listeria monocytogenes* (*L. mono*) contamination. We isolated *L. mono* from Smoked Ham (FDA Sample Number 133736) and Turkey breast (FDA Sample Number 122767) remnants that were previously used to prepare sandwiches, and were in the cold storage room to be used for future sandwich production.

Listeria monocytogenes is a pathogenic organism that can cause serious and sometimes fatal infections in young children, frail or elderly people, and others with weakened immune systems. Although healthy individuals may suffer only short-term symptoms such as high fever, severe headache, stiffness, nausea, abdominal pain and diarrhea, *Listeria* infection can cause miscarriages and stillbirths among pregnant women.

The U. S. Army notified you in June 2001 that they had isolated *L. mono* from your salami and cheese sandwiches sampled in May 2001. Additionally, the Army sample results revealed high aerobic bacteria levels (1,400,000 – 43,000,000 CFU/gm) in your Turkey and Cheddar, Salami and Cheese and Ham and Swiss sandwiches.

During our inspection, we observed inappropriate food handling and sanitation practices as outlined on the Form FDA-483, Inspectional Observations issued to you at the close of the inspection June 12, 2001. These practices included the failure to handle food appropriately to prevent contamination, and the failure to store food ingredients in a proper manner to prevent contamination.

For these reasons, we regard the products manufactured at your facility to be adulterated within the meaning of Section 402(a)(4) of the Act in that they are prepared, packed and held under conditions which may render them injurious to health.

We acknowledge the corrective actions you have implemented at your facility since the inception of the FDA inspection June 7, 2001. However, the actions you outlined in your response have not addressed all our concerns. Specifically, while you cleaned and sanitized your facility and implemented new cleaning and sanitization procedures, your approach was piecemeal and did not consider the re-use of remnants for further sandwich production. It is these remnants we found positive for *Listeria monocytogenes* during our inspection. We therefore have no assurance that you have not re-contaminated your facility and are not manufacturing adulterated products.

The above identification of violations is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to assure that your establishment is in compliance with all requirements of the federal regulations. Moreover, it is your responsibility to produce safe products. You should take prompt action to prevent further violation of the Act. Further violation of the Act may result in regulatory action without further notice, which can include seizure of your products and/or injunction of your firm.

Please notify this office in writing within 15 working days of receipt of this letter of the specific actions taken to correct the noted violations and prevent their recurrence. If corrective actions can not be completed within 15 working days, state the reason for the delay and the time within which corrections will be completed. Your written response should be directed to the attention of:

Thomas L. Sawyer
Director, Compliance Branch
Food and Drug Administration
19900 MacArthur Blvd., Suite 300
Irvine, CA 92612

Additionally, due to the serious concerns we have over the effectiveness of your corrective actions, we request that you contact this office within five (5) days of receipt of this letter to schedule a meeting. You may schedule this meeting by calling the district office at 949-798-7714 and arranging a mutually agreeable date and time.

Sincerely,

Alonza E. Cruse
District Director